From: Tegeris, John (OS/ASPR/BARDA) (CTR) [john.tegeris@hhs.gov]

Sent: 5/3/2017 7:40:17 PM

To: Maher, Carmen (FDA/OC) [Carmen.Maher@fda.hhs.gov]; Sadove, Elizabeth (FDA/OC)

[Elizabeth.Sadove@fda.hhs.gov]; Ross, Jennifer (FDA/OC) [Jennifer.Ross@fda.hhs.gov]; Nalubola, Ritu (FDA/OC) [Ritu.Nalubola@fda.hhs.gov]; Flamm, Eric (FDA/OC) [Eric.Flamm@fda.hhs.gov]; Zborowsky, Ashley (FDA/OC) [Ashley.Zborowsky@fda.hhs.gov]; Epstein, Laura (FDA/CVM) [Laura.Epstein@fda.hhs.gov]; Hartman, Mark

[Hartman.Mark@epa.gov]; McNally, Robert [Mcnally.Robert@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Milewski, Elizabeth [Milewski, Elizabeth@epa.gov]; Wozniak, Chris

[wozniak.chris@epa.gov]; Jennings, Susan [Jennings.Susan@epa.gov]; Layne, Arnold [Layne.Arnold@epa.gov]; Rosenblatt, Daniel [Rosenblatt.Dan@epa.gov]; Petersen, Lyle (CDC/OID/NCEZID) [lxp2@cdc.gov]; Beard, Charles (Ben) (CDC/OID/NCEZID) [cbb0@cdc.gov]; Koonin, Lisa (CDC/OID/NCIRD) [lmk1@cdc.gov]; Kovacs, Gerald (OS/ASPR/BARDA) (CTR) [Gerald.Kovacs@hhs.gov]; Seals, Jonathan (OS/ASPR/BARDA) [jonathan.seals@hhs.gov];

Craven, Mark (OS/ASPR/BARDA) [Mark.Craven@hhs.gov]; Knight, Antoinette (OS/ASPR/BARDA)

[Antoinette.Knight@hhs.gov]; Costero-Saint Denis, Adriana (NIH/NIAID) [E] [acostero@niaid.nih.gov]; Leissa, Brad G (FDA/CDER) [Brad.Leissa@fda.hhs.gov]; Lueptow, Rebekka (HHS/ASPR/BARDA) [Rebekka.Lueptow@hhs.gov];

Tegeris, John (OS/ASPR/BARDA) (CTR) [john.tegeris@hhs.gov]

CC: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]; Disbrow, Gary (OS/ASPR/BARDA) [Gary.Disbrow@hhs.gov];

Schafer, Julie (OS/ASPR/BARDA) [Julie.Schafer@hhs.gov]; Little, James (OS/ASPR/BARDA) [James.Little@hhs.gov]

Subject: Interagency Meeting with Oxitec/Intrexon; Wed May 17, 10am-12pm ET...

Hi All,

Hope the full team of interagency colleagues is doing well. On behalf of Rick Bright (BARDA Director) and those of us in the trenches, let me first start with a big thank you to everyone here for your willingness to participate in the meeting with Oxitec/Intrexon regarding their genetically modified mosquito vector control platform. This meeting is now officially scheduled for Wed May 17 from 10am-12pm ET. BARDA is set to host the meeting in the O'Neill federal building where we are headquartered, (200 C Street, DC, SW; mighty Elm Conference Room located on the 2nd floor). We would like a strong in-person turnout for the meeting, so thanks to all in advance for making the trip to DC if at all possible. I will send out the formal invite soon (by COB Thurs), to serve as a placeholder on respective Outlook calendars and complete with all the necessary details/meeting logistics.

Given that there has been the additional challenge for Oxitec due to dual jurisdiction/oversight by FDA and EPA for the regulatory process given inherent complexities with this type of development program, many of us think a USG only precall to align on our collective current thinking would be a wise idea. We will try to arrange this for likely later next week (~Thurs May 11) or early the following week (~Mon May 15). We also envision providing Oxitec time to make a presentation and to provide a list of questions to guide the open discussion then. Our goal is to ensure that by the end of the meeting the direct path forward for their specific development/product goals will be clearly articulated by our USG group in a unified way. Always easy to reach day or night on cell [Ex. 6-Personal Privacy] should anyone have anything they would like to discuss in the interim. Look forward to seeing many familiar faces and to meeting several new colleagues then! With much appreciation,

Best, John